PATENT
Attorney Docket No. EURA-007/00US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Gopi M. VENKATESH et al.

Application No.: 10/619,924 Confirmation No.: 7145

Filed: July 15, 2003 Group Art Unit: 1615

For: CONTROLLED RELEASE POTASSIUM CHLORIDE TABLETS Examiner: TRAN, Susan T.

U.S. Patent and Trademark Office
Customer Window, **Mail Stop AF**
Randolph Building
Alexandria, VA 22314

PRE-APPEAL BRIEF REQUEST FOR REVIEW

In response to the Final Office Action of December 24, 2008, Applicants respectfully request reconsideration of the above-identified application in view of the following remarks.

Remarks begin at page **2** of this Reply.

No amendments accompany this Reply.

REMARKS

I. Rejection of claims 35 under 35 U.S.C. § 103(a):

Claims 1-5, 7-27, and 29-31 stand rejected over Gantt (WO 01/43725 A1) in view of Bins (US 4,777,044), and claims 1-35 stand rejected over Gantt in view of Vilkov (US 5,807,579).

A. No *Prima Facie* Case of Obviousness (Friability and Dissolution Profile)

Applicants' claims recite tablets (and processes for their production) with a friability of ≤ 0.3% and a dissolution profile of % potassium chloride released at 2, 4, and 8 hour time points.

Applicants respectfully submit that the combination of Gantt and Bins or Vilkov fails to properly support *prima facie* obviousness. The references do not expressly teach tablets having ≤ 0.3% friability, individually or in combination. Bins and Vilkov are silent on friability, and Gantt merely mentions that certain tablets have "low friability" or "not more than 1.5%."[1] Furthermore, none of these references (individually or in combination) teach tablets that provide or would provide the claimed release profile. Gantt is silent as to release at the 2- and 4-hour time points, and the prophetic statement that its tablets "will exhibit...not more than 40% in one hour"[2] in no way suggests about 30-50% release at 2 hours or about 60-75% release at 4 hours. Bins' tablets dissolve completely after only 6 to 7 minutes,[3] evidencing that Bins' tablets do not exhibit the claimed dissolution profile. Vilkov does not mention any release data at all.

Therefore, no combination of Gantt, Bins, and Vilkov explicitly teaches the claimed friability or dissolution profile.

B. Improper Inherency Rejection under 35 U.S.C. § 103(a)

The Examiner apparently argues that Bins or Vilkov inherently teaches the claimed friability and shifted the burden to Applicants to prove otherwise.[4] Applicants respectfully submit that such an inherency rejection is improper. As a matter of law, an obviousness rejection cannot be predicated on a property inherent or unknown at the time of the invention. MPEP §

---

[1] Gantt at page 1, last line and page 5, lines 12-16.
[2] Page 5, lines 20-23.
[3] Col. 3, ll. 17-18. Bins' dissolution conditions are artificial intestinal juice at 7.5 pH, compared to purified water in the claims.
[4] Office Action dated December 24, 2008, at page 5, lines 3-5.

2141.02. Rather, an inherency rejection under Section 103 is only proper when the prior art composition appears to be identical to or the same as the claimed composition. MPEP § 2112(III). But the Examiner acknowledged on the record that Gantt's tablets are not identical to those claimed.[5] Therefore, the Examiner's rejection for inherent disclosure of the claimed friability in the prior art is improper.

Furthermore, the standard for inherency requires that the property is necessarily present each and every time or necessarily flows from the teachings of the cited art. MPEP § 2112(IV). The Examiner has not met that standard here. Regarding friability, Gantt's teaching of tablets with "low friability" or "not more than 1.5%" in no way implies that all such tablets necessarily have $\leq 0.3\%$ friability but in fact contemplates levels five times higher than those claimed. Regarding the dissolution profile, Gantt's teaching of "not more than 40% [release] in one hour" in no way suggests that about 30-50% necessarily releases at 2 hours or about 60-75% necessarily releases at 4 hours.

Accordingly, Applicants respectfully submit that the Examiner has not established *prima facie* obviousness based on inherent disclosure of the claimed friability or dissolution profile.

A. Improper Burden Shift to Prove Claimed Properties Not Present

The Examiner improperly shifted the burden to Applicants to prove that the prior art tablets do not have the claimed friability. As a matter of law, the Office may only shift the burden after showing a sound basis for believing that Applicants' and the prior art products are the same. MPEP § 2112.01(I). Here, the Examiner not only did not provide such a basis, the Examiner did the opposite by conceding that Gantt (presumably the closest prior art of record) does not describe compositions identical in structure or composition to those claimed.[6] Thus Applicants have no burden to prove that the tablets of the cited references do not meet the claimed $\leq 0.3\%$ friability.

---

[5] Office Action dated December 24, 2008, at page 2, line 16 and page 3, lines 15-16; Office Action dated May 5, 2008, at page 3, line 3 and page 4, lines 3-4.
[6] Id.

II. Rebuttal of *Prima Facie* Case under 35 U.S.C. § 103(a)

The Examiner improperly failed to consider Applicants' rebuttal evidence of nonobviousness. The Examiner must evaluate objective evidence relevant to obviousness (MPEP § 2145), including comparative data in the specification intended to illustrate the claimed invention (MPEP § 716.01(a)). Applicants have previously explained how the comparative data of friability and hardness data in Applicants' specification shows a 9- to 16-fold improved hardness and 20-fold improved friability, compared to compositions even more similar than Gantt's.[7] Yet the Examiner has failed give any consideration of Applicants' objective evidence of nonobviousness.

Apparently in response to Applicants' comparative results, the Examiner improperly cited *Ex parte Obiaya*,[8] which stands for the proposition that *prima facie* obviousness is not rebutted by merely recognizing a latent property present in the prior art. MPEP § 2145(II). Applicants respectfully submit that *Obiaya* is inapplicable here, where Applicants' data compares the same properties (hardness and friability) identified in the prior art.

III. Rejection of Claims 16, 27, and 33 under 35 U.S.C. § 103(a)

Applicants' claims 16, 27, and 33 recite a compressible blend or tablet "substantially free of lubricants," and claim 33 further recites an optional "surfactant." Applicants' specification clearly defines "lubricant" to encompass magnesium stearate and "substantially lubricant-free" to exclude magnesium stearate in amounts typically used for lubrication.[9]

Contrary to Applicants' definitions, the Examiner concluded that claims 16, 27, and 33 must encompass magnesium stearate because Xilinas (US 2008/0276673) identifies that ingredient by another name (surfactant).[10] However, Xilinas' use of "surfactant" is simply irrelevant to claims 16 and 27, which do not mention a surfactant. Regarding claim 33, the Examiner's interpretation that this claim both includes magnesium stearate as a "surfactant" yet simultaneously excludes it as a "lubricant" is simply unreasonable and inconsistent with Applicants' definitions in the specification (impermissible under MPEP § 2111.01(III)).[11]

---

[7] Response dated September 12, 2008, at page 17, lines 3-8.
[8] Office Action dated December 24, 2008, at page 8, lines 12-18.
[9] Page 10, paragraphs [0024] and [0026], and page 11, paragraph [0028].
[10] Office Action dated December 24, 2008, at page 8, line 20 to page 9, line 3.
[11] *See* Response After Final, dated June 22, 2009, at pages 8, lines 7-16.

Under the only reasonable interpretation consistent with the specification, Applicants respectfully submit that the rejection of these claims is improper because Bins and Vilkov teach away from tablets "substantially free of lubricants," and Gantt does nothing to discredit their teachings.[12] Because the Examiner improperly adopted an unreasonable and erroneous interpretation of this term, the Examiner has not considered these teachings away as evidence of nonobviousness (required under MPEP § 2145(X)(D)).

For the reasons stated above, Applicants respectfully request that the rejection be withdrawn and submit that the present application is in condition for allowance.

Except for issue fees payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-1283. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. 1.136(a)(3).

Dated: June 24, 2009

Respectfully submitted,
COOLEY GODWARD KRONISH LLP

By: Leigh Warren
Leigh M. Warren
Reg. No. 59,548

COOLEY GODWARD KRONISH LLP
CUSTOMER NUMBER 58249
ATTN: Patent Group
777 6th Street, NW, Suite 1100
Washington, DC 20001
Tel: (202) 842-7867
Fax: (202) 842-7899

[12] *See* Response After Final, dated June 22, 2009, at pages 8, line 18 to page 9, line 4.